510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K033059

B. Analyte:
Herpes simplex virus

C. Type of Test:
Enzyme-Linked Immunosorbent Assay

D. Applicant:
Trinity Biotech USA

E. Proprietary and Established Names:
Trinity Biotech Captia Herpes Group IgG Enzyme-Linked Immunosorbent Assay

F. Regulatory Information:

1. Regulation section:
   866.3305
2. Classification:
   Class III
3. Product Code:
   LGC
4. Panel:
   83

G. Intended Use:

1. Intended use(s):
   The Trinity Biotech Captia Herpes Group IgG Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative determination of IgG antibodies in human serum to *Herpes simplex* virus. The Herpes Group IgG ELISA kit may be used to determine serologic status in females of child bearing age, and to evaluate paired sera for the presence of seroconversions of IgG as an aid in the diagnosis of *Herpes simplex* virus infection.
2. Indication(s) for use:
   The Herpes IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for qualitative determination of IgG antibodies in human serum to *Herpes simplex* virus. The Herpes Group IgG ELISA kit may be used to determine serologic status in females of child bearing age, and to evaluate paired sera for the presence of a seroconversion of IgG as an aid in the

diagnosis of *Herpes simplex* virus infection. It is not intended for determining the type of *Herpes simplex* virus.

3. Special condition for use statement(s):
   Not Applicable
4. Special instrument Requirements:
   Single or dual wavelength microplate reader with 450 nm filter

H. Device Description:

This is an ELISA kit that contains *Herpes simplex* virus (MacIntyre strain, Vero cell Propagated virus is harvested by disrupting the cells, pelleted and solubilized) antigen coated microassay plate in a 96 well configuration, serum diluent, cutoff calibrator, a high positive, low positive, and negative control, horseradish-peroxidase conjugate, Chromogen/substrate solution, wash buffer and stop solution.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Herpes Group IgG ELISA Test System
2. Predicate K number(s):
   K963645
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Detect H. pylori IgG antibodies in human serum	Detect H. pylori IgG antibodies in human serum
Reagents	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)
Technology	ELISA	ELISA
Reagents	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop
Procedure	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm
Calculations	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor
Differences		
Item	**Device**	**Predicate**
None	None	None

J. Standard/Guidance Document Referenced (if applicable):
Not Applicable

K. Test Principle:
Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e. antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate Tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H2SO4, the contents of the wells turn yellow. The color, which is proportional to the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Not Applicable. This is a change in the distributor only. The performance characteristics were established in K963645.
    b. *Linearity/assay reportable range:*
    Not Applicable
    c. *Traceability (controls, calibrators, or method):*
    Not Applicable
    d. *Detection limit:*
    Not Applicable
    e. *Analytical specificity:*
    Not Applicable
    f. *Assay cut-off:*
    Not Applicable
2. Comparison studies:
    a. *Method comparison with predicate device:*
    Not Applicable
    b. *Matrix comparison:*
    Not Applicable
3. Clinical studies:
    a. *Clinical sensitivity:*
    Not Applicable
    b. *Clinical specificity:*
    Not Applicable
    c. *Other clinical supportive data (when a and b are not applicable):*
    Not Applicable

4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   Not Applicable

M. Conclusion:

The Trinity Biotech Captia Herpes Group IgG ELISA is substantially equivalent in performance to the predicate device for the identification of *Herpes Simplex* Virus in human serum.